

Remarks

Amendments To The Claims

Applicants have amended the claim 1 recitations regarding characterization of the second phase of the stair-stepped profile to recite “about 5 and about 9” hours and characterization of the third phase of the stair-stepped profile to recite “by about 9 hours following ingestion during the third phase.” Support for these amendments is found, *e.g.*, on page 11, lines 7–13; and Table 1 and Table 2 on page 12, of the specification.

Applicants have rewritten claim 2 and claim 4 in dependent form, properly depending from claim 1 and claim 3, respectively.

It is unclear from the record whether the amendments to claims 1 and 3 set forth in applicants’ March 30, 1999 Amendment were entered. Accordingly, applicants have re-entered those amendments to the Listing of Claims set forth above. Specifically, the amendments replace the phrase “drug-induced hepatotoxicity” with the phrase “treatment limiting hepatotoxicity and treatment limiting elevations in uric acid or glucose levels or both.” The amendments are supported at page 44, first paragraph, of the specification and tables III, IV, V, VI, and VII at pages 33 through 41 of the specification, for example.

Applicants have also amended the claims in response to the outstanding rejections, as discussed more fully below. None of the amendments constitutes new matter.

Claims 1-3 stand rejected under 35 U.S.C § 112, first paragraph, as being “indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” More particularly, the Examiner contends that the phrase “suitable for oral administration once a day” renders claims 1 and 3 indefinite.

Applicants believe that the phrase “suitable for oral administration once a day” is not indefinite, as the Examiner contends. Read in light of the specification, that phrase clearly defines the formulations of this invention as intermediate release nicotinic acid formulations, exhibiting a specific stair-stepped absorption profile, which are orally administered once a day. Nevertheless, in order to expedite prosecution, applicants have amended claims 1 and 3 (and, accordingly, the claims dependent therefrom) to recite that the intermediate release nicotinic acid formulations of this invention are in a once per day oral dosage form. This amendment is supported in the specification at page 1, lines 12-14, for example.

The Examiner also contends that in claims 2 and 3, which recite “3 phases”, the subject matter does not clearly define the absorption state of the third phase. In the Examiner’s view, claim 2 does not define nicotinic acid absorption for the third phase and claim 3 only defines the percentage of nicotinic acid absorbed for the first and second phase.

Applicants have amended claim 2 to recite the nicotinic acid absorption mean for the “first and second” phases. Support for the amendment is found, *e.g.*, on page 11, lines 7-13; and Table 1 and Table 2 on page 12, of the specification. Applicants have

amended claim 3 to recite that the nicotinic acid dose administered in the second phase is between about 5 and about 9 hours. Applicants have further amended claim 3 to recite "the remainder, if any, of the nicotinic acid dose administered is absorbed during the third phase." Support for the amendment is found, *e.g.*, on page 11, lines 7-13; and Table 1 and Table 2 on page 12, of the specification.

As a result of the foregoing, it is respectfully submitted that the present application and all pending claims, including claims 1-4, are in clear condition for allowance. Should the Examiner have any questions or require additional information or clarification, Applicants request that the Examiner contact the attorney of record at (305) 523-3643.

Respectfully submitted,



Karen Messick, Esq.
Registration No. 46,256
Attorney for Applicants

1001 Brickell Bay Drive
25th Floor
Miami, Florida 33131
Tel: (305) 523-3643
Fax: (305) 377-4076